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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/466,325	12/17/1999	CYNTHIA BRISCOE	99.305	1025

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MOTOROLA, INC.
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EXAMINER	
SINES, BRIAN J	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 08/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/466,325	BRISCOE ET AL.
	Examiner	Art Unit
	Brian J. Sines	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-63 and 84-103* is/are pending in the application.

4a) Of the above claim(s) *84-103* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 36 – 63, drawn to an integrated device for performing biochemical analysis, classified in class 422, subclass 68.1.

II. Claims 84 – 103, drawn to a method of making an integrated device formed via the sintering together of green sheet layers, classified in class 438, subclass 14.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the claimed device structure may be manufactured using either a sintering or lamination step.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Newly submitted claims 84 – 103 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The method of making the claimed device requires the step of sintering the green sheet layers together, thereby forming a substantially monolithic device structure, whereas the claimed device structure comprises a substantially monolithic device structure comprising a plurality of green sheet layers. The claimed device structure apparently does not require the sintering step in its fabrication.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 84 – 103 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. If the applicant intends to claim the method claims for the invention, then either a continuation or divisional application must be filed, which incorporate the method claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 36 – 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 36, apparatus claim 36 cannot be dependent upon method claim 84. This circular claim dependency renders claim 36 and dependent claims 37 – 63 indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 36 – 41, 49 – 52, 54, 56, 58 – 60, 62 and 63, are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayes et al. (U.S. Pat. No. 5,849,208 A) in view of Briscoe et al. (U.S. Pat. No. 6,544,734 B1). Regarding claims 36, 37 and 58, Hayes et al. teach a device (10) comprising: a plurality of well structures (40 – 42) for the parallel processing of a plurality of independently controlled molecular reactions, such as the polymerase chain reaction (PCR); a heating element (50 – 52); a cooling element (90); and a temperature monitoring element associated with each well structure (182) (see col. 3, lines 5 – 27; col. 4, lines 5 – 67; col. 5, lines 1 – 67; col. 6, lines 1 – 3; col. 8, lines 51 – 59; figures 1 – 4). Hayes et al do not specifically teach that the device may be fabricated as a substantially monolithic structure using green sheets. However, Briscoe et al. do teach the use of green sheets in the fabrication of a device, wherein the device may be used with a polymerase chain reaction in the analysis of samples containing DNA fragments (see entire reference). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the method of making an integrated or monolithic device using green sheets, as taught by Briscoe et al., in the fabrication of the device used for performing and analyzing the results of a polymerase chain reaction, as taught by Hayes et al. The applicant is advised that the Courts have held that the construction of a one-piece,

integrated construction for a structure formerly disclosed in the prior art is within the ambit of one of ordinary skill in the art (see *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965)). Regarding claim 40, ceramic materials are well known in the art as being corrosion resistant as well as thermally insulating. Therefore, by incorporating the method of making, as taught by Briscoe et al., in fabricating a DNA analysis device, as taught by Hayes et al., the resulting monolithic device structure would further comprise a thermally insulating ceramic material separating the well structures of the device. Regarding claim 38, Hayes et al. teach the incorporation of resistive heating elements (54) (see col. 5, lines 62 – 66). Regarding claim 39, Hayes et al. teach that the well structures comprise a thermally conductive material (58) (see col. 5, lines 62 – 67; col. 6, lines 1 – 3; figure 2). Furthermore, regarding claim 39, as discussed above, the resulting monolithic device structure would further comprise a thermally insulating ceramic material separating the well structures of the device. Regarding claim 41, Hayes et al. teach that the materials used in the construction of the device may incorporate polyimide polymeric material (see col. 4, lines 5 – 25). It would have been obvious to one of ordinary skill in the art to incorporate known materials being either thermally conducting or thermally insulating, such as copper and polyimide, as taught by Hayes et al., in addition to ceramic materials, as taught by Briscoe et al., in the fabrication of the instant device. The Courts have held that the selection of a known material based upon its suitability for the intended use is within the ambit of one of ordinary skill in the art (see *In re Leshin*, 125 USPQ 416 (CCPA 1960)). Regarding claim 49, Hayes et al. teach the incorporation of a passive cooling system, such as through the incorporation of finned surfaces (col. 4, lines 63 – 66). Regarding claims 50 and 52, Hayes et al. teach the use of an active cooling system, such as a conventional

thermoelectric cooler device (see col. 4, lines 63 – 67; col. 5, lines 1 – 4). Regarding claim 51, Hayes et al. teach that heat sink (90) is secured or integrated to the second major surface face (24) with a thermally conductive adhesive (92) (col. 4, lines 63 – 66; figure 1). Regarding claims 54 and 56, Hayes et al. teach that the well structures may be sealed using a cover (780) (see col. 12, lines 47 – 62). Regarding claims 59 and 60, Hayes et al. teach that thin film thermocouples may be incorporated into portions of a polyimide layer comprising the substrate of the device (see col. 8, lines 51 – 65). Regarding claims 62 and 63, Haye et al. teach that terminals (56 & 57) or electrical connections are distributed three-dimensionally within the device structure (see col. 5, lines 51 – 61; figure 2).

Claims 42, 43 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayes et al. in view of Briscoe et al. as applied to claims 36 – 41, 49 – 52, 54, 56, 58 – 60, 62 and 63, above, and further in view of Anderson et al. (U.S. Pat. No. 6,168,948 B1). Regarding claims 42 and 43, Hayes et al. and Briscoe et al. do not specifically teach the use of parylene as a coating compound. Anderson et al. do teach the coating of channel and chamber surfaces with parylene in order to modify the surfaces to better accommodate a desired reaction (see col. 20, lines 27 – 44). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the use of parylene, as taught by Anderson et al., with the well structures of the instant device, as taught by Hayes et al. in view of Briscoe et al. The Courts have held that the selection of a known material based upon its suitability for the intended use is within the ambit of one of ordinary skill in the art (see *In re Leshin*, 125 USPQ 416 (CCPA 1960)). Regarding claim 55, Hayes et al. and Briscoe et al. do not specifically teach the use of sealing the well structures using a layer of mineral oil. Hayes et al. do teach that the cover (780) may comprise a

single removable portion that covers only the reaction chambers (see col. 12, lines 47 – 62). Hayes et al. also teach that the fluids containing the DNA material and the solvents will typically have a tendency to vaporize during thermocycling (see col. 13, lines 43 – 53). Anderson et al. do teach the use of mineral oil deposited over the top surface of the sample (see col. 22, lines 4 – 26). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the use of a layer of mineral oil, as taught by Anderson et al., with the instant device, as taught by Hayes et al. in view of Briscoe et al., in order to permit the evolution of gas while preventing execessive evaporation of fluid from the sample under analysis. The Courts have held that the selection of a known material based upon its suitability for the intended use is within the ambit of one of ordinary skill in the art (see *In re Leshin*, 125 USPQ 416 (CCPA 1960)).

Claims 44 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayes et al. in view of Briscoe et al. as applied to claims 36 – 41, 49 – 52, 54, 56, 58 – 60, 62 and 63, above, and further in view of Mathies et al. (U.S. Pat. No. 6,132,580 A). Regarding claim 44, Hayes et al. and Briscoe et al. do not specifically teach the use of a thin film resistive heater. Hayes et al. do teach that controllable resistance heater (5) is integrally formed within the substrate and that any heater having a heating element in thermal contact with a reaction chamber is suitable (see col. 5, lines 29 – 37). Mathies et al. do teach a device used for PCR amplification, wherein the device incorporates the use of a thin film resistive heater (4) deposited on the bottom surface of reaction wells (see col. 5, lines 22 – 63). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the use of thin film resistive heaters, as taught by Mathies et al., with the instant device, as taught by Hayes et al. in view of Briscoe et al., in order to provide effective heating and thermal cycling control of the samples contained

within the wells of the device during analysis. Regarding claim 57, Hayes et al. and Briscoe et al. do not specifically teach that the cover further comprises means for heating the well structures. Mathies et al. do teach that two or more heating elements may be incorporated in the reaction chamber and that the heating elements may be extended beyond the boundaries of the reaction chamber in order to reduce the potential for temperature gradients within the sample contained within the well structure (see col. 5, lines 45 – 63). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate a cover further comprising a means for heating the well structures, as suggested by Mathies et al., with the instant device, as taught by Hayes et al. in view of Briscoe et al., in order to provide for the effective heating of the samples contained in the well structures during thermocycling by preventing or reducing the potential for temperature gradients, which could adversely affect the results of the PCR amplification.

Claims 45, 46 and 61, are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayes et al. in view of Briscoe et al. as applied to claims 36 – 41, 49 – 52, 54, 56, 58 – 60, 62 and 63, above, and further in view of Garner (U.S. Pat. No. 5,241,363 A). Hayes et al. and Briscoe et al. do not specifically teach the use of a metal wire resistive heater. Hayes et al. do teach that controllable resistance heater (5) is integrally formed within the substrate and that any heater having a heating element in thermal contact with a reaction chamber is suitable (see col. 5, lines 29 – 37). Garner does teach the incorporation of a metal wire resistive heater (138) in a device used for PCR amplification. Garner teaches that the heater wire (138) is positioned around the orifice bottom (128) and the passageway (126) of the disclosed apparatus (see col. 9, lines 5 – 44; figures 8 & 9). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the use of metal wire resistive heaters, as taught by Garner, with the instant

device, as taught by Hayes et al. in view of Briscoe et al. , in order to provide for effective heating and thermal cycling control of the samples contained within the wells of the device during analysis.

Claims 47, 48 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayes et al. in view of Briscoe et al. as applied to claims 36 – 41, 49 – 52, 54, 56, 58 – 60, 62 and 63, above, and further in view of Christel et al. (U.S. Pat. No. 6,369;893 B1). Hayes et al. and Briscoe et al. do not specifically teach the use of an integrated heating system which uses either column and row electrical addressing or substantially individual electrical addressing. Hayes et al. do teach that controllable resistance heater (5) is integrally formed within the substrate and that any heater having a heating element in thermal contact with a reaction chamber is suitable (see col. 5, lines 29 – 37). Hayes et al. also teach the use of a programmable controller (940) for a heater control (920) for controlling thermal cycling (see col. 14, lines 5 – 16). Christel et al. teach a device which uses an addressing system for process control (see col. 17, lines 40 – 67; col. 18, lines 1 – 63; col. 19, lines 5 – 41). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the addressing system, as taught by Christel et al., with the instant device, as taught by Hayes et al. in view of Briscoe et al., in order to provide for the effective thermal cycling control of each of the addressable well structures of the device. Hayes et al. and Briscoe et al. do not specifically teach the use of an integrated optical sensor system. Christel et al. do teach an improved system for optically interrogating reaction mixtures for analyzing the results of PCR amplification (see col. 3, lines 40 – 67; col. 4, lines 1 – 65). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the improved optical interrogating system, as taught by Christel et al., with the

instant device, as taught by Hayes et al. in view of Briscoe et al., in order to provide for the effective analysis of the products resulting from the PCR amplification studies.

Response to Arguments

Applicant's arguments with respect to claims 36 – 63 have been considered but are moot in view of the new ground(s) of rejection.

Claims 36 – 63 are product-by-process claims. The applicant is advised that product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. Eventhough product-by process claims are limited by and defined by the process of making, determination of patentability is based upon the product itself (see MPEP section 2113).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Faris et al. teach microchannel plate technology incorporating the use of green sheet fabrication. Burdon et al. teach the use of green sheets in the fabrication of microfluidic devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (703) 305-0401. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

August 11, 2003

Jill Warden
Supervisory Patent Examiner
Technology Center 1700